REMARKS

Claims 51-65 are pending and have been examined on the merits.

In the Office Action, claims 51-65 are rejected under 35 U.S.C. 112, ¶ 1 for allegedly failing to comply with the written description requirement.

Applicant respectfully traverses the rejection.

The subject matter of claims 51-59 is directed to an isolated monoclonal antibody or fragment thereof, comprising a light chain variable (V_L) domain comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 43, SEQ ID NO: 44 and SEQ ID NO: 46 and a heavy chain variable (V_H) domain comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 45 and SEQ ID NO: 47. The subject matter of claims 60-65 is directed to the pharmaceutical composition comprising the antibody or antibody fragment thereof recited in claims 51-59.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003).

As an initial matter, Applicant respectfully submits that the Examiner's citation of the standard of the written description requirement for a broad generic claim is misplaced (*e.g.*, page 3 of the Office Action).

As set forth above, claims 51-65 are not broad generic claims identifying a genus, but are rather directed to specific isolated monoclonal antibodies with light and heavy chain variable domains of well defined amino acid sequences or to their pharmaceutical compositions.

Accordingly, the citation of the standard of a written description involving a chemical genus is irrelevant to the presently pending claims.

Second, the Examiner has taken the position that the art does not consider that the claimed antibodies and fragments recited in claims 51-59, described solely by amino acid sequences of VH or VL, is adequately described according to the definition of antibody (*e.g.*, page 3, point 8 of the Office Action).

The Examiner has also taken the position that the term "pharmaceutical composition" recited in claims 61-65, indicates that the claimed antibodies are intended to be used in clinical preparation, that a "pharmaceutical composition" requires showing clinical benefit and that the state of the art indicates that it is not certain if all antibody or antibody fragment can be a medicine providing clinical benefit (*e.g.*, pages 4-5 of the Office Action).

However, these comments are irrelevant with regard to a claim rejection for an allegedly lack of written description.

To comply with the written description requirement of 35 U.S.C. § 112, ¶ 1, each claimed limitation must be expressly, or implicitly, or inherently supported in the originally filed disclosure. *In re Robins*, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA 1970).

As set forth above, independent claims 51 and 59, the only independent claims, recite an isolated monoclonal antibody or fragment thereof, comprising a light chain variable (V_L) domain comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 43, SEQ ID NO: 44 and SEQ ID NO: 46 and a heavy chain variable (V_H) domain comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 45 and SEQ ID NO: 47.

Further, claims 61-65 are directed to pharmaceutical compositions comprising pharmaceutical carriers and the monoclonal antibodies or antibody fragments recited in claims 51-59.

Applicant respectfully submits that the originally filed disclosure satisfy the written description requirement for the presently claimed subject matter.

For example, the specification discloses the amino acids corresponding to SEQ ID NO: 43, SEQ ID NO: 44, SEQ ID NO: 45, SEQ ID NO: 46 and SEQ ID NO: 47 in Figures 10A, 10B and 10C. Furthermore, Example 2 describes how to obtain the isolated monoclonal antibodies correspondent to those amino acid sequences (*e.g.*, from page 22 to page 32) and the definition of pharmaceutical composition is found on page 12, lines 13-24 and on page 13, lines 7-11.

Thus, one skilled in the art can conclude that each claim limitation is supported by the originally filed disclosure and that the inventor had possession of the claimed invention.

Finally, a description as filed is presumed to be adequate unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

That is, it is the Examiner who has the initial burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976).

Applicant respectfully submits that for the following reasons the Examiner has not met his burden.

As set forth above, the presently claimed subject matter is directed to isolated antibodies or to their pharmaceutical compositions comprising the isolated antibodies with a light chain and heavy chain variable domains as recited in claims 51 and 59.

According to the Examiner, the art does not consider adequately described the claimed antibody defined by the amino acid sequences VH or VL according to the definition of an antibody or does not teach that an antibody can be a medicine for treating all diseases if the antibody is capable of reacting with any antigen (*e.g.*, pages 3-4 of the Office Action).

However, as set forth above, this is not the correct standard to sustain a *prima facie* claim rejection for lack of written description. Moreover, the law establishes that a general allegation of unpredictability in the art is not a sufficient reason to support a rejection for lack of adequate written description. *Hyatt v. Dudas*, 492 F.3d 1365, 1370, 83 USPQ2d 1373, 1376 (Fed. Cir. 2007).

Thus, it is irrelevant what the definition of antibody is or that one of ordinary skilled in the art could not know what specific diseases the claimed antibody or fragment thereof treats. Because the reaction antigen/antibody is specific and selective, once the sequences of the light and heavy chain variable domains are known, a person skilled in the art is be capable of extrapolating the correspondent antigenic sequences without undue experimentation and with reasonable expectation of success.

Most importantly, the presently claimed subject matter is not directed to a method of treatment of a specific disease, but rather is directed to specific antibodies which are well described and supported by the specification.

Accordingly, for all these reasons, Applicant respectfully requests that the rejection of claims 51-65 under 35 U.S.C. § 112, ¶ 1, be reconsidered and withdrawn.

Conclusion

This response is being filed within the shortened statutory period for response, thus, no additional fees are believed to be due. If, on the other hand, it is determined that further fees are necessary or any overpayment has been made, the Commissioner is hereby authorized to debit or credit such sum to Deposit Account No. 02-2275.

Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

An early and favorable action on the merits is earnestly solicited

Respectfully submitted

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